

B4
Another drug that can be used to treat SPR infection is metronidazole, sold under the trade name FLAGYL®. The patient takes 500 mg twice per day for six weeks.

Please amend the paragraph on page 12, lines 5-7, to read as follows.

B5
Yet another drug that is effective in treating SPR infection is ofloxacin, sold under the trade name FLOXIN®. The patient takes 400 mg twice per day for two weeks.

In the Claims:

Please cancel claims 3-4. Kindly amend claims 1-2, 5-6, 9, 12, 14, 16, and 17 as follows.

B6
Sub D3
1. (Amended) A biologically pure culture of a single-celled organism, Spiky Rotating Cells (SPR), wherein said organism is a protozoan and comprises the following characteristics:
(i) a spherical shape measuring approximately 7-8 μm ; (ii) a protozoan having spiky membrane projections; (iii) a protozoan having a refractile cell membrane; (iv) a protozoan exhibiting rotatory motility; (v) a protozoan, said protozoan forming periodic colonies of 2 to 10,000 cells; (vi) a protozoan, said protozoan living in an extracellular environment; and (vii) causes disease in humans.

2. (Amended) The biologically pure culture of claim 1, wherein said organism has the biological characteristics of ATCC Deposit No. PTA-2129.

B7
Sub D3
5. (Amended) A method of diagnosing an SPR infection in a human patient, said

method comprising the steps of:

a) obtaining a sample from said patient; and

b) testing said sample for the presence of SPR, wherein the presence of SPR indicates an SPR infection.

6. (Amended) The method of any of claims 5, 22, 23, or 24, wherein said patient is a male, and wherein step a) comprises collecting said sample from the urethra of said male patient, wherein said sample is a secretion found in the urethra of said male patient.

9. (Amended) The method of claim 8, wherein said testing comprises admixing said sample with saline and examining said sample by microscopy.

10. (Amended) The method of any of claims 5, 22, 23, or 24, wherein said patient is a female, and wherein step a) comprises collecting a sample from the vagina of said female patient, wherein said sample is a cervico vaginal secretion from said female patient.

12. (Amended) The method of any of claims 5, 22, 23, or 24, wherein said patient has a skin eruption or lymph node abscess, and wherein the sample of step a) comprises a secretion from said skin eruption or abscess.

14. (Amended) An instrument for collecting a sample from a male patient, wherein said sample comprises urethral secretions, said instrument comprising:

a) a handle portion;

B10
Conclude
b) attached to said handle portion, a means for collecting secretions from the reproductive system of said male patient, wherein said collecting means comprises a loop; and

c) a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes into contact with said sample.

B11
16. (Amended) An instrument for collecting a sample from a female patient, wherein said sample comprises cervico vaginal secretions, said instrument comprising:

a) a handle portion;

b) attached to said handle portion, a means for collecting cervico vaginal secretions from said female patient, wherein said collecting means comprises a loop; and

Sub D1
c) a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes into contact with said sample.

17. (Amended) A method of treating an SPR infection in a patient, said method comprising:

a) diagnosing said SPR infection, and

b) upon obtaining a positive diagnosis in step a), administering to said patient an SPR-inhibiting amount of an anti-SPR agent selected from the group consisting of itraconazole, ofloxacin, and metronidazole.

Please add new claims 18-34.

B12 11/12
18. (New) The culture of claim 1, wherein said colonies are 2 to 1000 cells.

19. (New) The culture of claim 1, wherein said extracellular environment is skin, fluid of the genital tract, or the extracellular fluid of other organs.

20. (New) The culture of claim 1, wherein said disease is nongonococcal urethritis.

21. (New) The culture of claim 1, wherein said organism proliferates in Diamond's media.

22. (New) A method of diagnosing nongonococcal urethritis, or a propensity thereof, in a human patient, said method comprising the steps of:

- a) obtaining a sample from said patient; and
- b) testing said sample for the presence of SPR, wherein the presence of said SPR indicates nongonococcal urethritis or a propensity for developing said nongonococcal urethritis.

23. (New) A method of diagnosing nongonococcal urethritis, or a propensity thereof, in a human patient, said method comprising the steps of:

- a) obtaining a sample from said patient;
- b) testing the pH of said sample from said patient; and
- c) testing said sample for the presence of SPR,

wherein said sample having both a pH greater than 6.0 and the presence of SPR indicates nongonococcal urethritis, or a propensity thereof, in said patient.

B12
cont.
24. (New) A method of diagnosing nongonococcal urethritis, or a propensity thereof, in a human patient, said method comprising the steps of:

- a) obtaining a sample from said patient;
- b) inoculating Diamond's Medium with said sample;
- c) culturing said sample, wherein said SPR organism selectively proliferates; and
- c) confirming the presence of said SPR organism in said sample.

25. (New) The method of claim 24, wherein said sample is obtained using the instrument of claim 14 or 16.

26. (New) The method of claim 24, wherein said Diamond's Medium comprises 5 mg/mL cycloheximide and 0.4 mg/mL chloramphenicol.

27. (New) The method of claim 24, wherein said sample comprises 2-3 μ L of fluid from the genital tract or the extracellular fluid of other organs from said human patient.

28. (New) The method of claim 24, wherein said culturing comprises (a) inoculating 2-3 μ L of said sample into 3 mL of said medium, (b) loosely stoppering said inoculated medium, and (c) incubating said inoculated medium at 36°C in a 5% CO₂ enhanced atmosphere for 3-4

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days.

29. (New) The method of claim 24, wherein said confirming the presence of said SPR organism is performed by examining said cultured organism by microscopy.

B12
Cont.
30. (New) The method of claim 24, wherein prior to step b), the pH of said sample is tested, and wherein a pH greater than 6.0 indicates an SPR infection.

31. (New) The method of any of claims 5, 22, 23, or 24 wherein said SPR has the biological characteristics of ATCC Deposit No. PTA-2129.

32. (New) The method of any of claims 5, 22, 23, or 24 wherein said SPR is a protozoan and comprises the following characteristics: (i) a spherical shape measuring approximately 7-8 μm ; (ii) a protozoan having spiky membrane projections; (iii) a protozoan having a refractile cell membrane; (iv) a protozoan exhibiting rotatory motility; (v) a protozoan, said protozoan forming periodic colonies of 2 to 10,000 cells; (vi) a protozoan, said protozoan living in an extracellular environment; and (vii) causes disease in humans.

33. (New) The method of claim 11, wherein said instrument includes a loop for secretion collection.

34. (New) The method of claim 33, wherein said testing comprises admixing said